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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,260	11/14/2003	Signe Thorning Mejlhede	P69290US0	8054

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EXAMINER

HEITBRINK, JILL LYNNE

ART UNIT PAPER NUMBER

1732

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/712,260

Applicant(s)

MEJLHEDE ET AL.

Examiner

Jill L. Heitbrink

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 24 is/are pending in the application.
- 4a) Of the above claim(s) 11-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/14/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-10 and 24 in the reply filed on May 24, 2006 is acknowledged. The traversal is on the ground(s) that the amended claims have an integral relationship between the method and the catheter. This is not found persuasive because as stated in MPEP 806.05(f) "A product defined by the process by which it can be made is still a product claim (In re Bridgeford, 357 F.2d 679, 149 USPQ 55 (CCPA 1966)) and can be restricted from the process if the examiner can demonstrate that the product as claimed can be made by another materially different process; defining the product in terms of a process by which it is made is nothing more than a permissible technique that applicant may use to define the invention." In the case, the product can be made by another materially different process such as extrusion or gas-assisted injection molding (no core used).

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 7 and 8 contain the trademark/trade name ECDEL, C-FLEX, LUPOLEN, PELLETHANE, TECOTHANE CARBOTHANE. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the

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claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the polymer and, accordingly, the identification/description is indefinite.

5. Claim 24 recites the limitation "the inlets" in line 1. There is insufficient antecedent basis for this limitation in the claim. The examiner believes that claim 24 was intended to be dependent from claim 2.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4 and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by McFarlane Pat. No. 5,510,065.

8. McFarlane discloses a method for injection molding a flexible (col. 1, lines 39 and 40) catheter having a hub (formed in the upper portion of the cavity adjacent the proximal end 25) and a tube-shaped part (formed below the hub) as shown by the cavity

shape in Fig. 1. The molten polymer is feed into a mold having a core 22 which has a cylindrical part (shown in the elongated portion of the cavity in Fig. 1) and a cone-shaped part (shown above the cylindrical part of core 22). The core is removed from the catheter when the polymer is sufficiently cured and the catheter is removed from the mold when the polymer is sufficiently cured (col. 12, lines 1 and 2). The catheter is cured to its final state in the mold since McFarlane describes the product being solidified when removed (col. 12, lines 1 and 2). The molten polymer is supplied to the mold via at least two inlets (injection ports 60).

9. Claims 1, 2, 6, 7, 8 and 10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Glocker et al. WO 90/00960.

10. Glocker discloses a method of producing soft needle catheters on core with a sleeve to assist removal as stated on page 3 of applicant's specification. Glocker discloses a method for injection molding (page 1, line 2). The core 2 is shown to have a cone shape in one mold half and a cylindrical shape in the other mold half, see Fig. 1. The mold separates perpendicular to the tube-shaped part at or just below the hub as shown in Fig. 1. The molten polymer is fed into a region of the hub or cone shape so that the injected polymer will move the sleeve 3 during filling of the cavity. The core is removed from the catheter when the polymer is sufficiently cured and the catheter is removed from the mold when the polymer is sufficiently cured (page 9, last paragraph). The catheter is cured to its final state in the mold (page 10, last paragraph). Glocker (page 5, first paragraph) discloses the molding of similar materials including copolymers of polypropylene.

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11.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1, 2, 7 and 8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jeffs Pat. No. 5,032,343.

14. Jeffs discloses a method for injection molding a flexible micro pipette having a hub (end portion 22) and a tube-shaped part (64) as shown by the cavity shape in Fig.

6. The molten polymer is injection molded using a core 80 which has a cylindrical part (92) and a cone-shaped part (88). The core is removed from the pipette when the polymer is sufficiently cured and the pipette is removed from the mold when the polymer is sufficiently cured since the pipette is used with the injection mold removed. The pipette is cured to its final state in the mold since Jeffs describes the product being used in the shape molded by the injection molding. The product molded being a catheter rather than a micro pipette does not limit the process being claimed since the dimensions are similar and the use of the product does not limit the method of producing the product. However, the use of the injection molding process to produce a catheter of similar dimensions and flexibility would have been obvious to a person of ordinary skill in the art in view of the article similarities. The injected material is polypropylene (col. 6, line 4).

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15. Claims 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over anyone of McFarlane Pat. No. 5,510,065, Glocker et al. WO 90/00960 or Jeffs Pat. No. 5,032,343 as applied to claim 1 above, and further in view of Goral et al. Pat. No. 6,630,086.

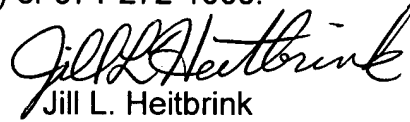
16. Goral (col. 9, lines 61-62) teach that the mold halves can be mated longitudinally or vertically. It would have been obvious to a person of ordinary skill in the art to separate the mold along the axis or perpendicular to the tube in any of the primary references since these are known alternatives in the art of molding catheters.

17. Goral teaches the selection of materials for the hub and tube equivalent to the in claims 7, 8 and 9. The process in Goral is gas assist injection molding rather than injection molding with a core. It would have been obvious to a person of ordinary skill in the art to use the material of Goral in the injection molding process of the primary reference since these material are known to be injection moldable and are known to be desired in medical catheters.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jill L. Heitbrink whose telephone number is (571) 272-1199. The examiner can normally be reached on Monday-Friday 9 am -2 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jill L. Heitbrink
Primary Examiner
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jlh